Adverse Event Reporting and Postmarket Surveillance at FDA's Center for Devices and Radiological Health

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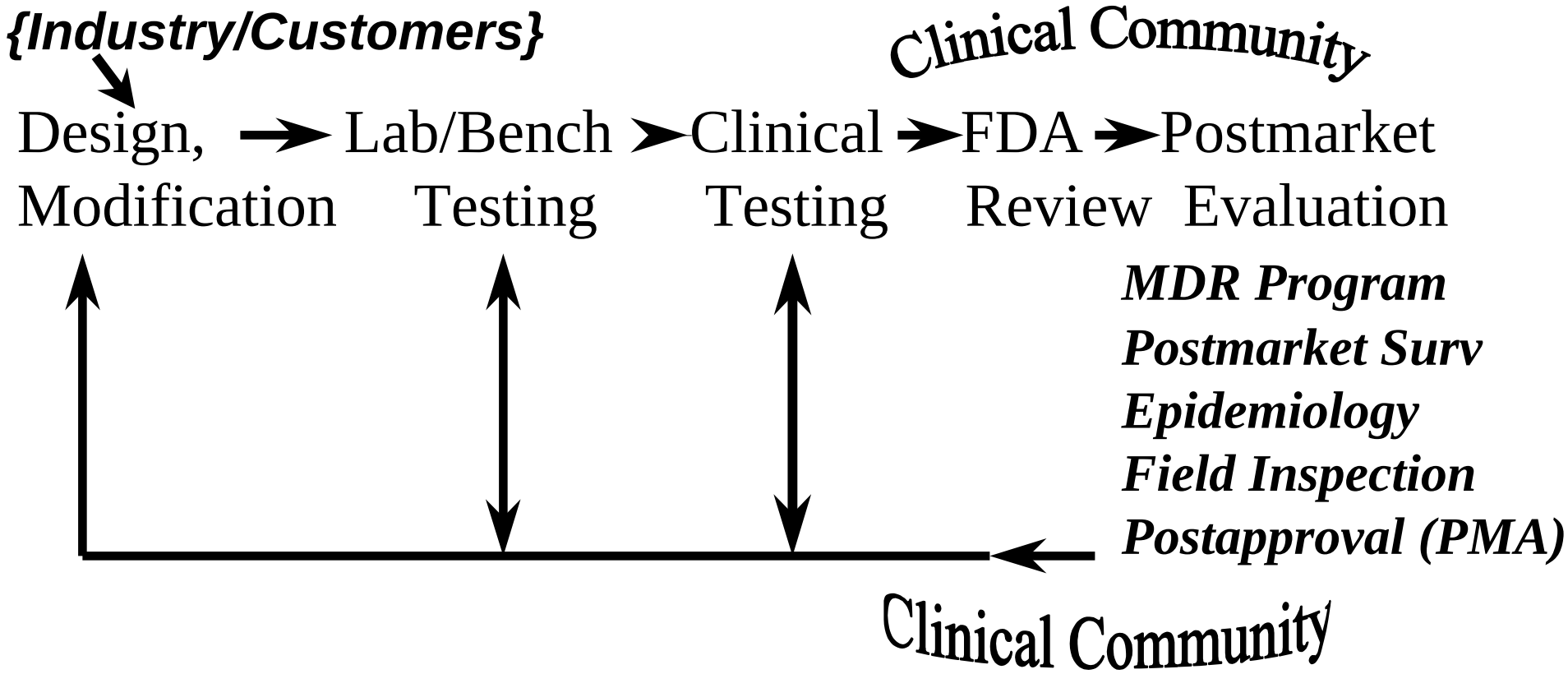
Presentation Objectives

- Provide a context for adverse event reporting and postmarket surveillance
- Describe the multiple methods of medical device surveillance at CDRH/FDA
- Discuss new initiatives in postmarket surveillance and the changes brought by the FDA Modernization Act of 1997

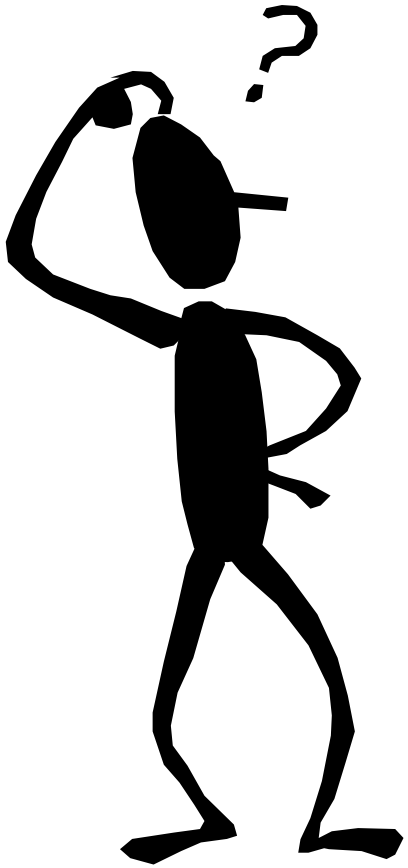
From Design to Obsolescence: Medical Devices and Center for Devices and Radiological Health, FDA



'Design' ⟶ Device evolution ⟶ 'Obsolescence'

Questions of Interest in the Postmarket Period

- Long term safety
- After clinical trials, performance of device in community practice
- Change of user setting (e.g., hospital to home)
- Unusual pattern of adverse events not requiring product recall



Questions of Interest and FDA Approaches in the Postmarket Period

- Long term safety
- After clinical trials, performance of device in community practice
- Change of user setting (e.g., hospital to home)
- Unusual pattern of adverse events not requiring product recall
- Postapproval study
- Epidemiology studies (e.g., case-control, secondary data bases)
- Postmarket surveillance
- Adverse event reports (Medical Device Reporting System)

The US Medical Device Reporting Program

- The mandatory US system for manufacturer reporting began in 1984
- SMDA 1990 changed MDR: add malfunction reports and mandatory user facility reporting
- Regulations to put 1990 law into effect established 1996: program is ***DYNAMIC***
- FDAMA'97 changed Postmarket surveillance and the User Facility reporting programs

Adverse Events: Medical Device Reporting Program (MDR)

- Manufacturers must (by law) report deaths and serious injuries or malfunctions (near incidents) if a medical device may have caused or contributed to the event
- All user facilities (hospitals, nursing homes, etc.) must report deaths to the FDA and serious injuries to manufacturers

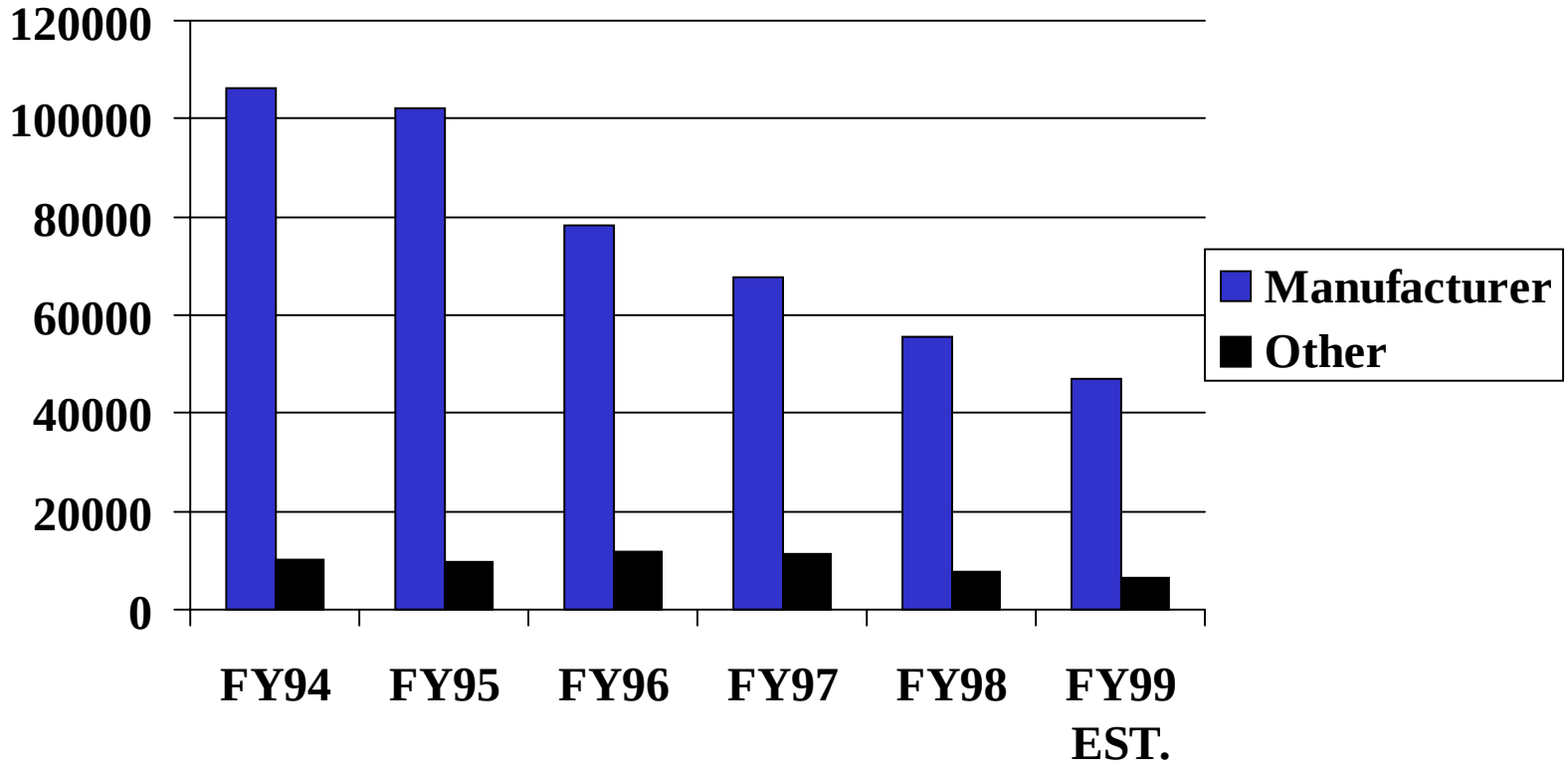
Features of the MDR Regulation

- Regulation adopted as final July 31, 1996
- Industry focused changes
  - *Deletion of per se rule, change in time frames*
  - Certification
  - US Designated Agent
  - Baseline reporting and “Denominator” data
- Adoption of regulations for user facilities

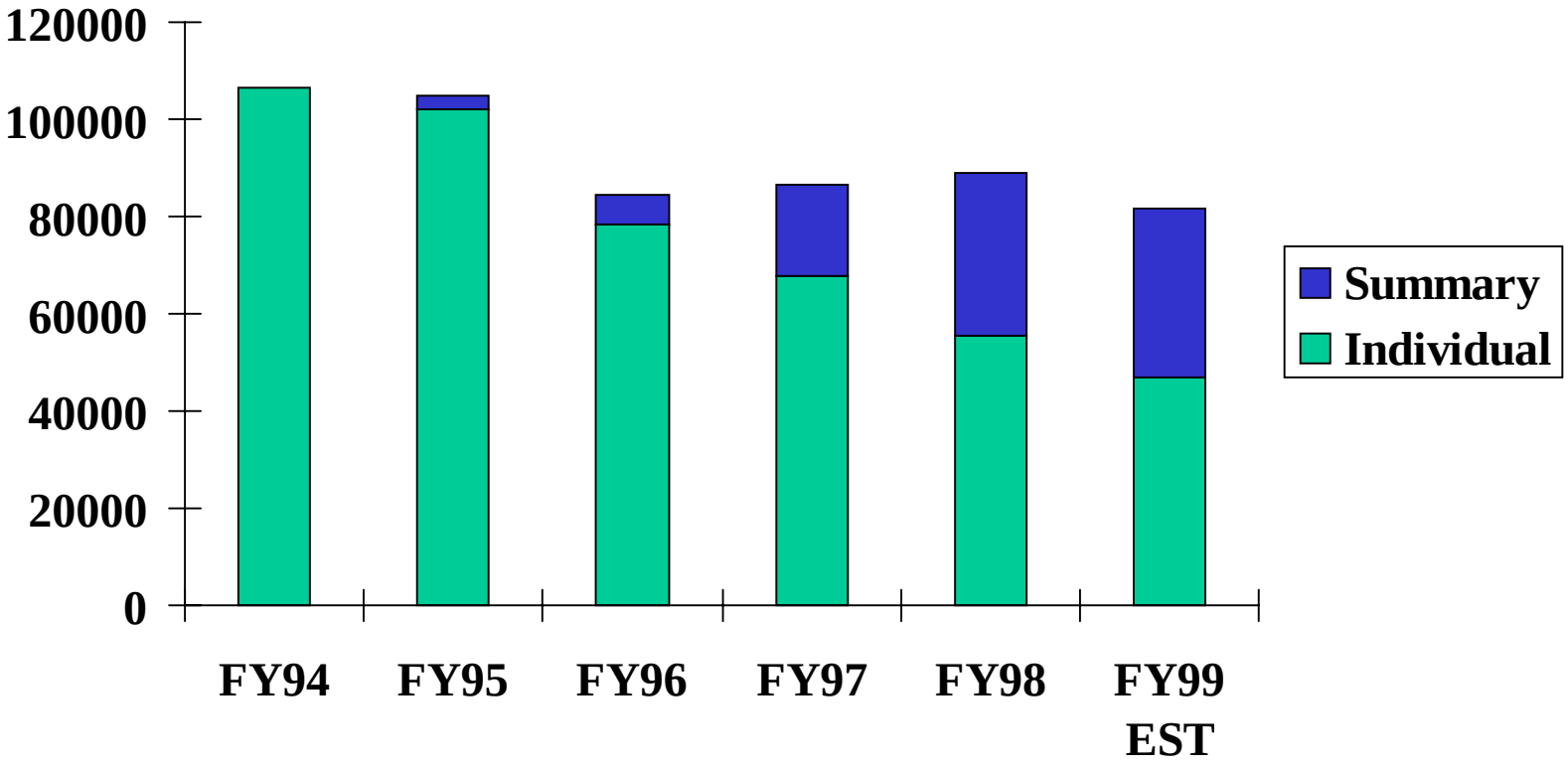
The MDR Program

- Beginning about 1992, FDA received over 100,000 medical device adverse event reports/yr
- Information includes device specifics, event description, event date, patient characteristics
- Reports often have very limited information, but also provide critical signals to FDA

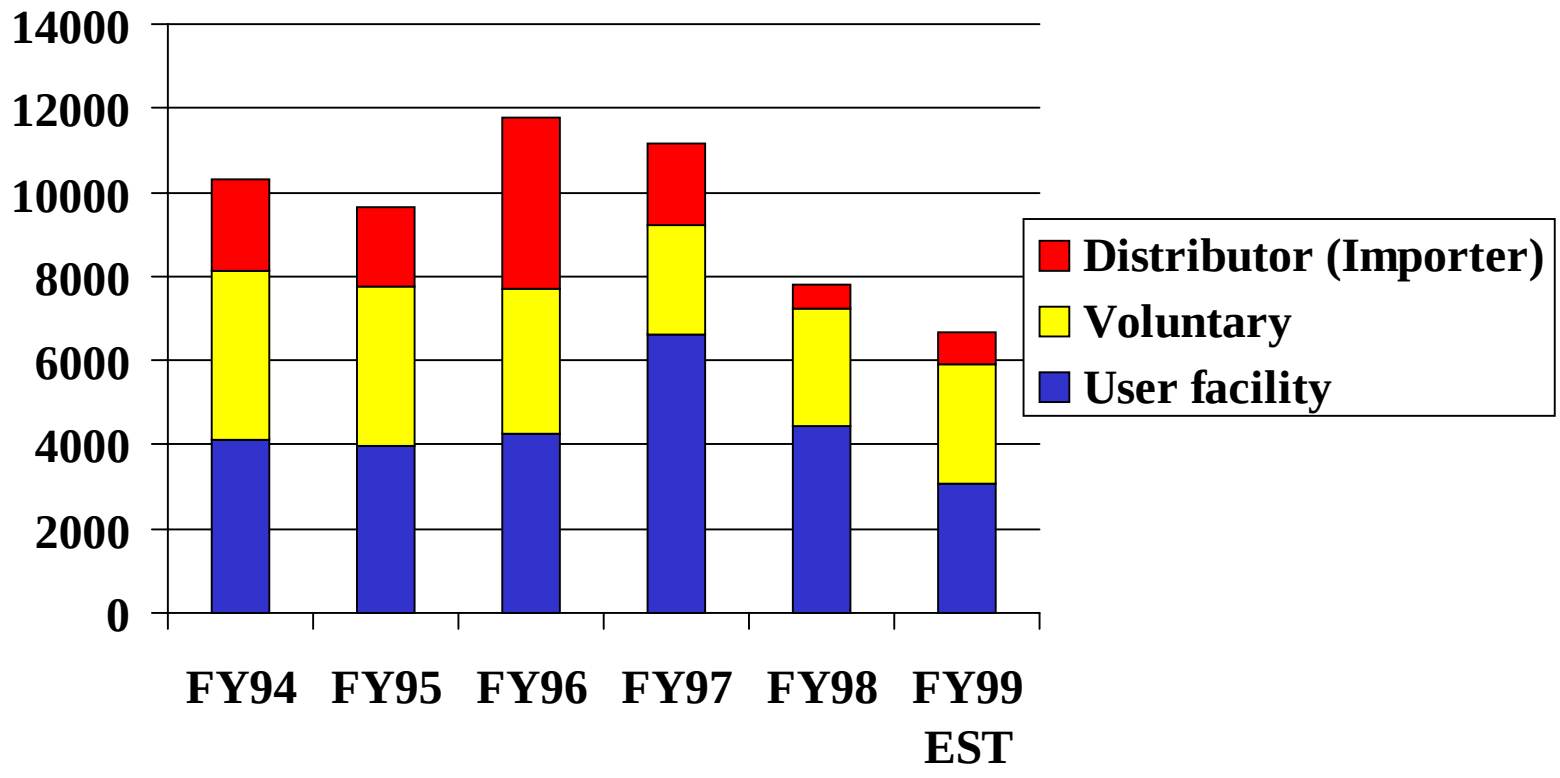
Reporting Trends with Manufacturers (Individual Reports) Fiscal Year 1994 - Present



MANUFACTURER REPORTS (Includes Summary Reporting)



Reporting Trends with Non-Manufacturers (Individual Reports)



Clinical Findings from MDR

- Oxygen cylinder explosions/fires
- Pulmonary artery catheters: biomaterial and sterilization issues (also clinical use issues)
- Core biopsy needles and metal shavings
- Fetal vacuum extractors: injuries and deaths
- Dialysis crisis: internal blood leaking

Actions Prompted by the MDR Program

- Directed inspection of mfr. or facility (radiation therapy)
- Product seizure (spontaneous combustion of latex gloves)
- Product recall (infusion pump)
- Additional study via postmarket surveillance (midline catheter)
- Patient/physician notification (lead fracture; dialysis units)

FDA Modernization Act of 1997 and Postmarket Issues

- MDR Program changes:
  - New specification of confidentiality of user facility information on MDR reports
  - FDA must present a plan for Sentinel Reporting in place of universal reporting
- Postmarket Surveillance changes:
  - Deleted required postmarket surveillance
  - Continued with FDA having discretionary postmarket surveillance authority
  - Added some restrictions, such as 3 year study limit

Recent Initiatives in MDR

- Summary reporting and reengineering
- Sentinel Surveillance System
- Nomenclature efforts
  - Working to harmonize ECRI with FDA
  - Participating in CEN sponsored effort to develop Global Medical Devices Nomenclature (GMDN)

SUMMARY REPORTING

- Goal: Reduce noise in the MDR system and improve the signal to noise ratio
- Approach: Allow periodic submission of well known, repetitive reports, in line item format
- Expect 38,000 summary reports in FY’99
- 45 manufacturers participating
- 52 exemptions
- New system in place for Jan. 2000

THE MEDICAL DEVICE SURVEILLANCE NETWORK (MeDSuN)

WHY CHANGE USER REPORTING?

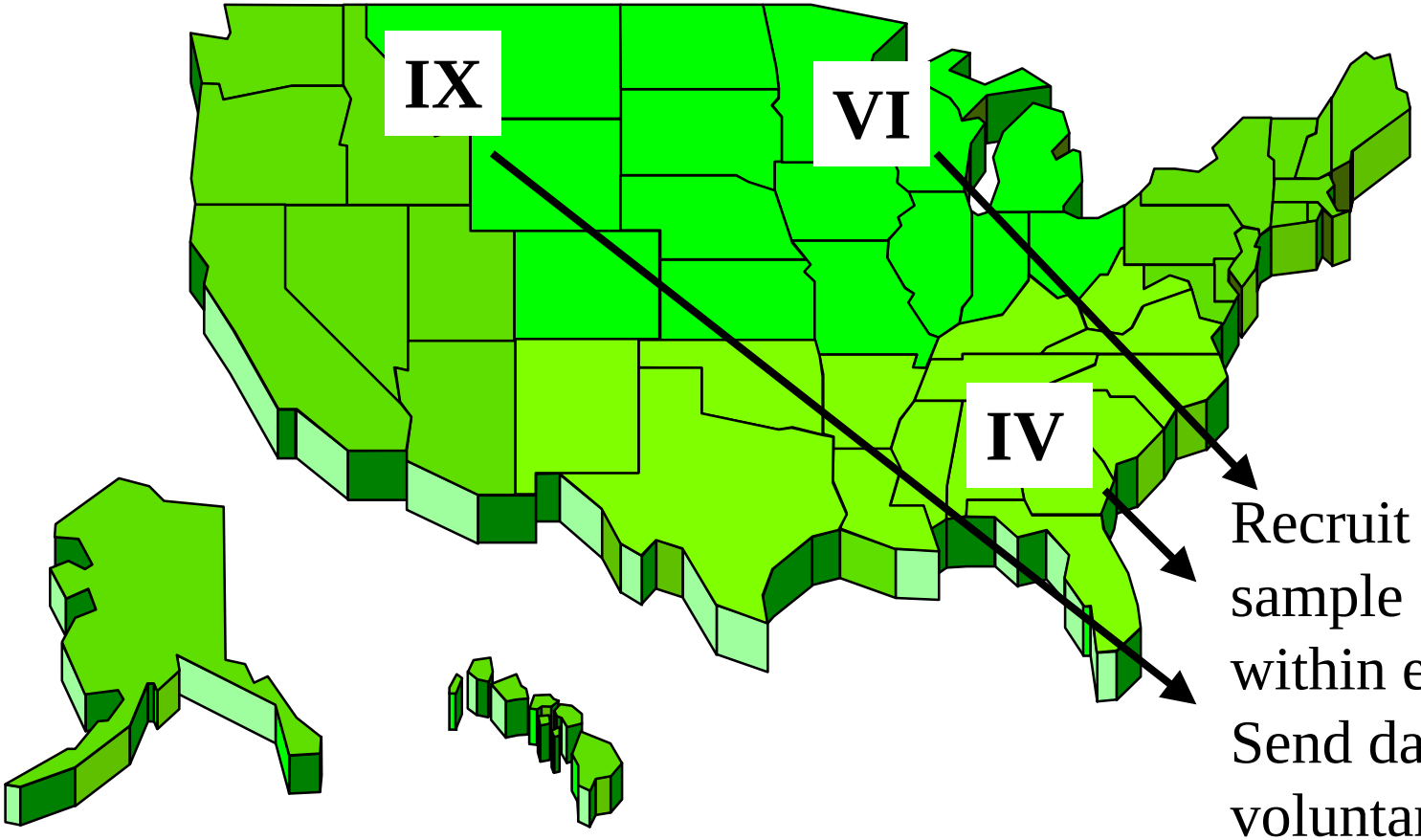
- **Underreporting / lack of quality data**
- **Lack of connection to clinical facilities**
- **Changes in conceptualization**
- **FDAMA**

Where Are We Now?

- **Pilot of 24 hospitals for one year completed and highly successful.**
- **Planning to implement larger “Phase 2” pilot - 50 facilities from 3 regions of country (total = 150).**
- **Request for Proposal for contractor to aid in Phase 2 development will be issued when funding received.**
- **Regulation to implement national program will be issued following Phase 2 experience.**

FDA: Management, Analysis, and Action

Coordinating Center: Maintain uniformity and quality control; Materials development; Advisory Group



Recruit probability sample of facilities within each region; Send data; Grassroots voluntary reporting

MeDSuN Impact on Manufacturers

- **Manufacturer reporting responsibilities remain unchanged.**
- **MeDSuN participating user facilities will send adverse event reports to manufacturers with more useful information about the device-related incident.**
- **Manufacturers able to be more proactive in preventing device-related deaths and serious injuries.**

Postmarket Surveillance Philosophy

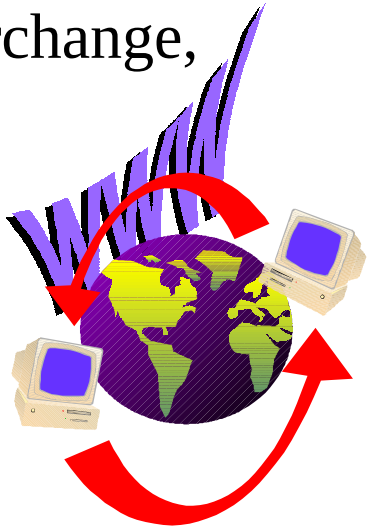
- Focus PMS on device areas with greatest potential
- Develop criteria to require PMS: allows discretion for FDA
- Development and availability of “useful” postmarket data

Factors Suggesting DPS Study

- “For cause”
- Complement to premarket
  - Changing premarket data requirements
  - Changing health care environment
  - Expanded patient population
- Downclassification or special controls
- Ability/need to evaluate long-term issues

The Future of MDR and PMS

- Medical Device Reporting
  - MeDSuN
  - Fewer individual reports, more summary
  - Electronic interchange, perhaps via WWWeb
  - Integration with Q.S.R.
  - International harmonization



- Postmarket Surveillance
  - More discretionary, less required PMS
  - More collaboration with industry and clinical community
  - Expanded access to different data sources, e.g., registries